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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,534	11/20/2001	Charles V. Lowry	0410008	9912
23405	7590	02/25/2004	EXAMINER	
HESLIN ROTHENBERG FARLEY & MESITI PC 5 COLUMBIA CIRCLE ALBANY, NY 12203			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S-AM

Office Action Summary

Application No.

09/989,534

Applicant(s)

LOWRY, CHARLES V.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 30-32 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-20 and 23-28 is/are allowed.
- 6) ☒ Claim(s) 1-16, 21, 22, 29 and 33-39 is/are rejected.
- 7) ☒ Claim(s) 40 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed December 3, 2003.

Claims 1-41 are pending in the instant application. Claims 30-32 remain withdrawn as being drawn to a non-elected invention. Claims 1-29 and 33-41 are under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 29, 2003, that is not addressed in this action has been withdrawn.

Applicant's arguments with respect to claims 1-16, 21, 22, 29 and 33-39 have been considered but are moot in view of the new ground(s) of rejection.

Specification

The use of the trademark pBS (i.e., pBluescript™) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. See MPEP§ 608.01(v). Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the Trademark pBluescript™ (i.e., pBS) in the claims. The relationship between a trademark and the product it identifies is sometimes indefinite, uncertain, and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark. See MPEP§ 608.01(v). Because the product as recited in the claim may change over time, the claim is indefinite as having undefined metes and bounds. **This is a new rejection that is not necessitated by amendment.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Prior to setting forth the rejections, the Office wishes to clarify several interpretations of the claims. The preamble of the product claims, wherein it is recited that the claimed products are “for use in monitoring the efficiency of a restriction endonuclease digestion” is given no patentable weight because this represents an intended use of a product, which is capable of being used for distinct alternative purposes, such as cloning. The kit claims (33-39) are also interpreted as an intended use of the products set forth in the kit, especially in light of the fact that the vectors claimed

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therein are applicable to multiple uses. Therefore, any teaching that anticipates the claimed vectors necessarily anticipates any kit thereof, as the contribution of the kit over the prior art is directly linked to the plasmids contained therein. It is also noted that the limitation "instructions for use" contains no patentable weight as it merely represents an intended use, and does not reflect upon the nature of the claimed product. Finally, with regard to the rejection of claims 21 and 22 (where applicable), the claims are interpreted as a product-by-process, where the process must confer a functional distinctness on the product that will distinguish it from the prior art (i.e., the plasmid cannot be made by another method); in the instant rejections, it is believed that the plasmid that results from the method can be produced by an alternative method, such as basic cloning techniques and/or vector construction, absent clear and convincing evidence to the contrary.

Claims 1-11, 29, 33-34, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsang et al. (*Biotechniques* 22:68, 1997; see the entire document; henceforth Tsang). **This is a new rejection that is not necessitated by amendment.**

Tsang teaches the construction of pRSC, an expression vector having the pUC19 backbone, and containing two independent multiple cloning sites (i.e., polylinkers) (see for example the first paragraph). The first polylinker is located 3' to the RSV promoter and contains a plurality of unique restriction sites, namely *KpnI* and *HindIII* (see Figure 1). The second polylinker is located 3' to the CMV promoter and contains a plurality of unique restrictions sites (different from those in the first polylinker), namely *EcoRV*, *NotI* and *XhoI* (see Figure 1). Since the pUC19 backbone possesses a bacterial origin of replication, and because pRSC has the capacity to replicate in *E. coli*, the pRSC vector must necessarily contain an origin of replication. Additionally, the vector contains at

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least two selectable markers, specifically the Ampicilin and Neomycin resistance genes. Furthermore, Tsang discusses growing the plasmids in large quantities for their use (see the sentence bridging the left and middle columns). Because Tsang teaches using pRSC for cloning purposes, it necessarily requires that the plasmid be digested with the appropriate restriction enzymes (and their respective buffers), thus the inclusion of the restriction enzymes and buffers is necessary in the teachings of Tsang.

Regarding the ability of the plasmid to produce a fragment of a specific length upon digestion of the plasmid, relative to the undigested plasmid, the following rationale is provided. The CMV promoter is approximately 600bp in length, and given the relative size of the SV40 PolyA sequence and blank sequence region (as depicted in Figure 1), the fragment between the two polylinkers is approximated at 1kb. The full-length plasmid is approximately 6.5 kb. Upon digestion of the plasmid with any two enzymes (one selected from each polylinker), the fragments produced will be approximately 1kb and 5.5kb each, representing 15% and 85% of the full sized plasmid. Absent evidence to the contrary, 85% is considered to be "about 80%" since there is no clear definition in the specification as to the nature of the term "about." As such, Tsang teaches each and every element of the claims set forth above in the rejection statement.

Claims 1-16 21-22 and 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Fussenegger et al. (*Biotech. And Bioengineer.* 57:1-10, 1998; see entire document; henceforth Fussenegger). **This is a new rejection that is not necessitated by amendment.**

Fussenegger teaches the construction of a set of 6 plasmids, called pTRIDENT (see for example the Abstract, and Figure 1). The pTRIDENT vectors comprise a pBS (i.e., pBluescript) backbone, which contains an Ampicillin resistance gene (selectable marker) and an *E. coli* origin of replication (ori). The pTRIDENT vectors also comprise multiple polylinker sites, specifically three distinct ones, each of which contains a number of unique restriction sites (see for example Figure 1). For example, in the first member of the set (pTRIDENT 1), the first polylinker contains the unique restriction sites *EcoRI*, *PstI* and *HindIII*, the second polylinker contains the unique restriction sites *NotI*, *FseI*, etc., and the third polylinker contains the unique restriction sites *SpeI*, *SfgI*, etc. Similar restriction site patterns can be found in the remaining vectors, which will not be addressed in detail here in the interest of brevity. Because these vectors are used for cloning purposes (see for example the Abstract), it necessarily requires that the plasmid be digested with the appropriate restriction enzymes (and their respective buffers), thus the inclusion of the restriction enzymes and buffers is necessary in the teachings of Fussenegger.

Regarding the ability of the plasmid to produce a fragment of a specific length upon digestion of the plasmid, relative to the undigested plasmid, the following rationale is provided. The distance between the *EcoRI* site in the first polylinker and the *BglII* site in the third polylinker is 2711 nucleotides in one orientation, and 1301 nucleotides in the other direction, giving fragments that are readily distinguishable from each other, one of which is approximately 67% of the length of the full length plasmid. This meets the limitation of at least 15%, and at least between 50-80% of the size of the full-length

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plasmid. The same assessment can be made with anyone of the pTRIDENT plasmids taught by Fussenegger. As such, Fussenegger anticipates the above-indicated claims.

Allowable Subject Matter

Claims 17-20 and 23-28 are allowed.

Claims 40 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

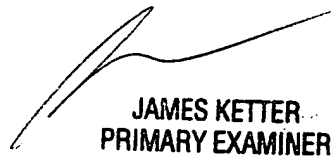
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER